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Proceeding	91177234
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The new platen for the Alaris Medley MSS LVP is distinguishable by the two spring-loaded metal buttons (indicated by the arrows).

reported overinfusions occurred when the pump was turned off).

Alaris's latest pump modifications. The company announced the availability of a modification for Medley LVP modules in a Product Modification Notice distributed on November 15, 2004. This modification involves widening the well at the top of the pumping channel so that an upper fitment placed outside the well will slide into the well when the door is closed. Alaris is contacting all user facilities to schedule the modification. The supplier estimates that the procedure should take two minutes per pump, including the time needed to clean and prepare the pump. ECRI has not tested the modification.

CONCLUSIONS

Uncontrolled gravity flow indisputably poses a serious risk to patients, especially when a patient becomes overmedicated with a high-alert drug. Overdelivery is also a major risk for patients with fluid restrictions.

The new platen reduces but does not eliminate the occurrence of gravity flow when an administration set is incorrectly loaded in an LVP. We have not tested the effectiveness of the wider-well modification, but we believe that it should reduce overinfusion if it allows a misloaded upper fitment to slide into the well as described. And although Alaris's user education materials can help reduce the occurrence of misloaded administration sets, we believe that users should not require special training to load sets. More importantly, it should not be possible to load any pump's administration set in a way that produces uncontrolled flow.

RECOMMENDATIONS

1. Alert users or other appropriate personnel to the problem and to our report.
2. Ensure that the modified platen (distinguishable by the presence of two spring-loaded metal buttons, as shown in the photo on this page) is installed in all Medley MSS LVP modules. If it hasn't been, install it or arrange for Alaris to install it.
3. Ensure that all Medley MSS LVP modules receive the wider-well modification.
4. Ensure that users are trained in correct tubing installation, which involves loading the set from top to bottom. Consider hanging the user education posters available on Alaris's Web site in care areas where these pumps are used, especially until Alaris effectively modifies the LVP to prevent gravity flow. This may help promote proper loading of the administration set.
5. For further information, contact Alaris at +1 (800) 854-7123, ext. 7812.

On the Web. More photos illustrating this problem accompany the December *Health Devices* at www.ecri.org.

UMDNS terms. Infusion Pump Administration Sets [16-579] ■ Infusion Pumps, General-Purpose [13-215]

Supplier. Alaris Medical Systems Inc., Subdivision of Cardinal Health Inc. [308442], San Diego, California (USA); +1 (800) 854-7123, +1 (858) 458-7000; www.alarismed.com ◆

You have probably noticed that we discuss "gravity flow" in this article but "free-flow" in the article on JCAHO's National Patient Safety Goal (page 430). We describe the differences between these terms on page 447.

Hazard Report

Medtronic Lifepak 12 May Not Function when Switching from AC to Battery Power

PROBLEM

Our staff routinely perform checks of our Medtronic Emergency Response Systems (ERS) Lifepak 12 defibrillator with the unit unplugged. However, if they power up the unit using battery power immediately after unplugging it, the service indicator comes on and the defibrillator may not function. No injuries have been reported, but this problem could delay a resuscitation attempt if staff must obtain another defibrillator.

DISCUSSION

The Lifepak 12 defibrillator/monitor can operate on AC line power or battery power. Medtronic ERS states that if the Lifepak 12 is removed from AC line power and is then turned on within two seconds, a power "sag" may occur as the unit transitions to battery power. The power sag may cause a microprocessor reset; depending on the timing of the reset, the unit's initialization sequence could be disrupted. This in turn could cause the unit to fail its internal checks, in which case an error code will be logged into the memory and the service indicator will illuminate.

This situation is described on page 7-6 of the Lifepak 12 operating instruction manual, which states: "The SERVICE indicator on the Lifepak 12 defibrillator/monitor may illuminate if you turn on the defibrillator/monitor and disconnect [the AC adapter] from the defibrillator/monitor or power source at the same time. Wait at least 2 seconds between disconnecting the power adapter and turning on the defibrillator/monitor regardless of the order of the actions." If the service indicator does come on because the device was powered up too soon, cycling the power will turn the service indicator off, and the device should function. (On page 8-14 of the operating manual, one of the corrective actions given for an illuminated service indicator is to "turn the device off then on again.")

SUPPLIER'S CORRECTIVE ACTION

Medtronic ERS has implemented revised software that addresses this timing issue. The revised software is incorporated in the power board (Part No. 3006237-007) of units manufactured after August 2003. The supplier states that because a specific sequence of events is required for this anomaly to occur, no widespread correction is planned.

Medtronic ERS states that replacement of the power board is covered by factory and extended warranties. (Lifepak 12 units for hospital use have a five-year warranty.) For units not under warranty, the customer will be charged the normal service rate (approximately $1,058, which includes the new board); alternatively, Medtronic ERS can provide the new board (for approximately $559), and customers can install it themselves. To arrange for service, or to receive an estimate for replacement, healthcare facilities should contact their local technical service representative directly or call +1 (800) 442-1142.

The supplier recommends being sure that users know how to proceed any time a service indicator illuminates.

RECOMMENDATIONS

Although this anomaly has a low probability of occurring, a resuscitation attempt may be delayed if the defibrillator

ECRI's Hazard Reports

A Hazard Report describes a possible source of peril, danger, or difficulty. We publish reports about those units in which we have identified a fault or design feature that *might*, under certain circumstances, place patients or users at risk. These reports describe the problem and ECRI's recommendations on how to correct or avoid it. Publication of a report on a specific brand name and model of device in no way implies that competitive devices lack hazardous characteristics.

When deciding whether to discontinue using a device that ECRI believes poses a risk, staff should balance the needs of individual patients, the clinical priorities, and the availability of safer or superior products against the information we provide. Clinical judgment is more significant than an administrative, engineering, or liability decision. Users can often take precautions to reduce the possibility of injury while waiting for equipment to be modified or replaced.

does not function and the user does not know that the power should be cycled. Facilities should do the following:

1. Alert users and other appropriate personnel to the problem and our report.
2. Healthcare facilities whose Lifepak 12 units are under warranty should replace their power board with a new board that includes the revised software. If your units are not under warranty, carefully assess the likelihood of the reported problem occurring at your facility. If you decide replacement is advisable, contact the supplier to inquire about installing a revised power board.
3. Train users to wait at least two seconds between disconnecting the power adapter and turning on the defibrillator/monitor, regardless of the order of these actions. Also train users to turn the unit off and back on if the service light is illuminated and the device will not turn on, charge, or discharge.

UMDNS term. Defibrillators, External, Manual [11-134]

Supplier. Medtronic Emergency Response Systems [363222], Redmond, Washington (USA); +1 (800) 442-1142, +1 (425) 867-4000; www.medtronic-ers.com ◆

Gravity Flow versus Free-Flow

In the Hazard Report that starts on page 443, we use the term **gravity flow** to describe an overdelivery of fluid that occurs when a pump is turned either on or off and its administration set is misloaded:

- When the pump is turned on and is operating, gravity flow will occur if the pumping mechanism isn't able to completely occlude the administration set tubing, which will allow additional flow (more than is intended). That is, there is a gravity component of flow during part of the pumping cycle in addition to the intended flow from the programmed flow setting.
- When the pump is turned off, gravity flow will occur if the pumping mechanism were stopped during the same portion of the pumping cycle that would allow gravity flow when the pump was operating.

Gravity flow could also occur if the pumping mechanism were damaged.

The term **free-flow** is commonly used to describe incidents in which the administration set has been removed from the pump and fluid flows due to gravity. Most often, this situation occurs on a pump with no free-flow protection when a manual clamp has not been closed before a set is removed from the pump. We discuss the presence or lack of free-flow protection on general-purpose, PCA, and ambulatory pumps in the article that starts on page 430. ◆

A Publication of the
HEALTH DEVICES SYSTEM

Health Devices System

Objectives

To improve the effectiveness, safety, and economy of health services by:

1. Providing independent, objective judgment for selecting, purchasing, managing, and using medical devices, equipment, and systems.
2. Functioning as an information clearinghouse for hazards and deficiencies in medical devices.
3. Encouraging the improvement of medical devices through an informed marketplace.

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Patient-Controlled Analgesic Infusion Pumps

UMDNS term. Infusion Pumps, Patient-Controlled Analgesic [16-924]

Summary. Patient-controlled analgesic (PCA) infusion pumps allow patients to self-administer doses of pain-relieving medication as needed, rather than having to summon a caregiver. The most significant risk when using these pumps is overmedication leading to narcotic-induced respiratory depression. Several current PCA pumps offer advanced error-reduction features designed to minimize the odds of an accidental overdose: dose error reduction systems, bar-code readers, and computer-based pump-programming systems that entail downloading infusion protocols via a hardwired connection to a PC. The availability of these features plays a dominant role in our ratings.

We tested 11 pumps from seven suppliers. Two pumps are rated Preferred because they offer easy-to-use advanced error-reduction features that have been proven effective in a hospital setting. Two other pumps offer computer-based programming and are rated Acceptable, although we note that not all facilities may be able to accommodate the workflow necessary to use the computer-based programming. The remaining pumps are rated Not Recommended because they lack advanced error-reduction features; although most of these pumps perform acceptably, better choices are available.

Technology Overview

About PCA Technology

Patient-controlled analgesic (PCA) infusion pumps allow patients to self-administer narcotic analgesics within the limits prescribed by a physician. PCA therapy is used for postoperative, obstetric, terminally ill, and trauma patients and is increasingly being used for less acute patients as well. PCA pumps deliver solutions intravenously, subcutaneously, or epidurally and allow patient activation by means of a pendant button on a cord connected to the pump or a button directly on the pump.

POLE-MOUNTED VERSUS AMBULATORY PUMPS

PCA pumps come in two main styles: larger pole-mounted pumps and smaller ambulatory-style pumps. Pole-mounted pumps are intended for bedside use, often in an inpatient setting; most offer limited ambulation time (around eight hours of battery life). They are typically syringe drivers that emphasize function for complex care, with larger display screens and easy-to-navigate menus that guide the clinician through the programming process. These pumps generally offer more computing power and therefore more comprehensive features, functions, and event logs. However, they are less versatile because they can only deliver medications that are available in syringes.

Ambulatory-style pumps are intended to be carried by the patient to allow ambulation in inpatient, outpatient, and home care settings; they may also be clamped to an IV pole. They are typically peristaltic pumps that deliver fluid from small bags or cassettes and emphasize portability and simplicity of programming. These pumps can run on batteries for several days, but they conserve both size and battery life by having smaller display screens and fewer programming options presented to the clinician during programming. (Most options must be tracked down under separate menus.) Most ambulatory-style pumps can deliver from a wide range of fluid containers such as bags, vials, syringes, and bottles, and this flexibility allows many of these pumps to offer other therapies such as total parenteral nutrition (TPN), continuous, or antibiotic infusion. It is common, especially in outpatient or home care settings, for an ambulatory-style pump to stay with one patient for an extended period of time, while pole-mounted pumps tend to be used on a variety of patients and for a limited period of time.

Both styles offer inherent advantages: Pole-mounted pumps offer more sophisticated guidance to the programmer, while ambulatory-style pumps offer the convenience of portability and the flexibility of using a single pump for more than one application. Facilities may use one or both styles in normal use, and many facilities select a style based on their drug purchasing practices. For example, a syringe driver is a poor fit for a facility that wishes to purchase pain medications in small bags; in addition, it cannot be used to deliver TPN or antibiotic therapy, since those medications are provided in volumes too large for syringes.

MULTITHERAPY VERSUS SPECIALIZED PUMPS

A growing trend in PCA pumps is the divergence of pumps that are increasingly multifunctional (i.e., those that can be used for therapies other than PCA) from pumps that are increasingly specialized for PCA therapy. For example, some ambulatory PCA pumps can also be used for therapies such as TPN, antibiotics, and chemotherapy. One pump we evaluated is modular: In addition to a PCA module, it has modules for large-volume general-purpose delivery and syringe delivery. A facility can choose to either standardize on one or a few models of multifunctional pumps for all infusion therapies (e.g., general-purpose, ambulatory, PCA, syringe) or purchase several models of pumps, each optimized for a particular therapy.

PCA THERAPY IN THE HOME

Traditionally, PCA therapy has been associated with use in an inpatient hospital setting. However, several trends, such as the decrease in length of stay after inpatient surgery, the rise of outpatient surgery (particularly in specialties such as orthopedics), and an increasing awareness of the need for pain control in palliative care, have resulted in PCA use in other care settings. PCA therapy is now provided in outpatient cancer clinics, surgery centers, and hospice care facilities, and by home healthcare providers.

Automatic programming functions, which are becoming available on PCA pumps (see Advanced Error-Reduction Features, below), can be beneficial in the home care setting. Our product ratings in this Evaluation take into account the suitability of the evaluated pumps for home care applications as well as for use within the hospital.

Safety Issues

HAZARDS AND ERRORS DURING PCA THERAPY

The use of a PCA pump entails more hazards than that of standard infusion pumps. The most notable hazard of PCA use is overmedication leading to narcotic-induced respiratory depression. ECRI continues to receive reports and investigate incidents of patient deaths caused by narcotic overinfusions resulting from the misprogramming of PCA infusion pumps. The incidents reported to and investigated by ECRI are typically associated with the entry (or acceptance by the pump) of an incorrect programming parameter such as drug concentration, bolus dose size, or continuous or basal flow rates. An erroneously programmed low drug concentration, for example, will cause a pump to deliver an excessive amount of the drug, causing an overdose. Another typical error is "switching" the basal and bolus dose amounts.

When the U.S. Pharmacopeia (USP) examined medication errors submitted to its MEDMARX and USP Medication Errors Reporting Programs between September 1998 and December 2004, the reported data indicated that the rate of patient harm in reports involving PCA pumps was 3.5 times higher than the overall rate of patient harm of all medication error reports, and about 30% of PCA errors were related to misprogramming.* This indicates that errors in PCA therapy are more likely to harm patients than errors in other types of medication administration. A search of the U.S. Food and Drug Administration's (FDA) Manufacturer and User Device Experience (MAUDE) database of reported device errors revealed that reports of PCA-related device errors were almost twice as likely to result in injury or death as reports of device errors involving general-purpose infusion pumps.**

About 30% of PCA errors are reportedly related to misprogramming.

Patients may also be harmed even if the pump's programming matches the medication order. PCA pumps are used primarily with powerful narcotic drugs, and the effects of these drugs may be difficult for caregivers to anticipate: A dose that is insufficient for one patient may oversedate another, depending on each individual's physiologic response. ECRI is also aware of several cases in which patients receiving pain medication from PCA pumps received dangerous and even lethal amounts of narcotics when family members or clinicians activated the pumps' delivery request button on the patient's behalf. Facilities need to be aware that allowing anyone other than the patient to press the delivery request button is a clear contraindication of PCA therapy and strongly warned against by ECRI,*** the Joint Commission on Accreditation of Healthcare Organizations (JCAHO),† and manufacturers of PCA infusion pumps.

REDUCING ERROR THROUGH STANDARDIZED PROTOCOLS

One way to keep overmedication incidents to a minimum is through the use of standardized protocols. PCA pumps are often programmed according to facilitywide protocols that allow for standardized drugs (typically fewer than four), concentrations, and dosing regimens for typical patient characteristics. For example, a facility may develop standardized protocols labeled "Morphine Post-Op" for standard postoperative pain control or "Morphine, Opiate-Tolerant" for patients who require higher doses of drug to achieve adequate pain relief. As for dosing protocols, these are implemented in the form of either a preprinted order sheet or a preset list in an order entry system.

Using standardized protocols reduces medication errors by limiting the number of choices a physician needs to make when prescribing (e.g., deciding between a 1 mg bolus with 5-minute lockout and a 2 mg bolus with 10-minute lockout) and by reducing transcription and programming errors related to hard-to-read orders. Hospitals can also use dosing protocols to standardize on one or a few concentrations of each drug, reducing the likelihood of medication errors due to selecting the wrong drug concentration when obtaining a drug vial or entering the concentration into the pump.

* Santell JP. Preventing errors that occur with PCA pumps. *US Pharm* 2005;30(1):58-60.

** Search on August 1, 2005, of all reports in MAUDE database for both devices by FDA product code and outcome (e.g., product code = MEA, outcome = death or injury). Of 3,260 reports for product code MEA (PCA pumps), 370 (11.3%) resulted in death or injury. Of 22,369 reports for product code FRN (general-purpose pumps), 1,253 (5.6%) resulted in injury or death.

*** ECRI. Triggering of patient-controlled analgesic pumps by clinicians or visitors could be lethal [hazard report]. *Health Devices* 2004 Jan; 33(1):24-5.

† Joint Commission on Accreditation of Healthcare Organizations. Patient controlled analgesia by proxy [online]. Sentinel Event Alert 2004 Dec 20 [cited 2005 Nov 15]. Available from Internet: http://www.jcaho.org/about+us/news+letters/sentinel+event+alert/sea_33.htm.

ADVANCED ERROR-REDUCTION FEATURES

As awareness of the risk of overmedication with PCA therapy continues to increase, many manufacturers are developing what we refer to as advanced error-reduction features, which can detect and prevent dose-related infusion errors and the programming of incorrect infusion settings.

Three Types

Three types of advanced error-reduction features are principally used for PCA pumps:

Bar coding. Integrated bar-code readers use automated pump programming, allowing a clinician to populate a pump's settings without manually entering the information into the pump. When a clinician scans a drug vial's bar code, pump settings such as drug name and concentration are entered automatically (and without human entry error) from the bar code. Some systems can also automatically populate the pump with patient-specific or drug-vial-specific dosing protocols and dosing limits.

Dose error reduction systems. Dose error reduction systems provide guided manual programming, using pump-based software to check programmed doses against preset limits stored in drug libraries that are downloaded to the pump. Limits are specific to a drug and to clinical location, application, or protocol profile. These systems alert clinicians to programmed doses that exceed these preset limits and can either require confirmation before beginning delivery (referred to as a soft limit) or, with some systems, not allow delivery at all (hard limit). Because pumps with dose error reduction systems store the alert and event log information that results from clinical use of drug libraries, hospitals can mine this data for insight into their own medication practices and to improve the drug libraries and clinical practice. (For further discussion, see "Infusion Pump Dose Error Reduction Systems" in the December 2004 *Health Devices*—particularly the opening section on using data from these systems for quality improvement.)

On these pumps, all safety software parameters (i.e., drug libraries) are contained in the pump. This arrangement eliminates the need to interact with a computer every time a pump receives initial programming, but it requires more memory and user menus to hold drug library data. It also requires locating all pumps to update drug library parameters if wireless data transfer is not available. (Often, drug libraries are updated when the pumps come in for preventive maintenance.)

Computer-based pump-programming software. Computer-based pump-programming applications also program pumps automatically, allowing a clinician to program a PCA pump by selecting and downloading one of a facility's preset dosing protocols from a computer to a pump via a wired connection. When a clinician sends a protocol to a pump, the pump is populated with a drug name, concentration, starting dose, time-based dosing limit, and lockout interval, thus eliminating entry errors in initial programming. In some cases, the pump receives protocol-specific dosing limits (analogous to those offered by dose error reduction systems) for subsequent reprogramming over the course of therapy. These programs can be useful in home care settings as well as in the hospital.

With these applications, all safety software parameters (i.e., protocol libraries) are housed in a PC and not in the

Advanced Error-Reduction Features: Pros and Cons

The advanced error-reduction features currently available for PCA pumps can significantly reduce the risks of accidental overmedication. However, no one feature addresses all aspects of PCA programming safety by itself—each has limitations.

Feature	Pros	Cons
Bar coding	Automatically populates pump settings; in some cases, includes patient- or drug-vial-specific protocols	Can't identify inappropriate continuous or bolus dose settings (unless these are contained in bar codes) or provide dosing limits on subsequent reprogramming
Dose error reduction system	Provides guided manual programming, alerting clinicians to doses that exceed preset limits	Doesn't ensure that right drug is selected from library; drug library must be updated to match clinical use
Computer-based pump programming	Automatically populates pump settings; in some cases, includes protocol-specific dosing limits	Protocols must be downloaded via hardwired connection to a PC, necessitating workflow changes; doesn't ensure that right drug is selected from library

pumps. This arrangement offers two advantages: First, pumps can offer safety software without needing larger, more complex (and possibly more expensive) data storage, displays, and user menus. Second, facilities can quickly revise dosing protocols by simply updating the protocols on the few computers used to program the pumps, eliminating the need to locate and update all PCA pumps. However, this arrangement also requires the clinician to interact with a PC (or perhaps a handheld computer) every time a pump receives initial programming for a patient. This practice is different from most current clinical practice, and the change in workflow may be a hurdle to some facilities. (For further discussion, see "Implementing Computer-Based Pump-Programming Systems" on this page.)

Computer-based pump-programming systems are only just becoming available, and as yet few hospitals are using them. Currently, more hospitals are using dose error reduction software and integrated bar-code readers.

Considerations with Error-Reduction Features

A major advantage of all three error-reduction technologies is that they encourage a facility to standardize on a limited number of drugs, concentrations, and dosing units customized to the facility's needs. ECRI believes that, when effectively implemented, these advanced features can be powerful tools for reducing infusion errors caused by misprogramming. Therefore, we believe that hospitals should require such features in the pumps they purchase.

Users need to recognize, however, that although each of these features offers safety benefits, each one individually has limitations (see the list of pros and cons on page 8). And because most suppliers currently offer only one error-reduction feature on their pumps, most products today don't offer as much protection as we'd like. For example:

- Most current pumps with dose error reduction systems and PC-based pump-programming systems have no

Implementing Computer-Based Pump-Programming Systems

Can You Accommodate Them in Your Hospital?

Computer-based pump-programming systems for patient-controlled analgesic (PCA) pumps use a hard-wired connection to a PC to download infusion protocols to the pump each time new programming is required. There are three basic ways in which this can be accomplished. The first is the most practicable; clinicians with whom we've spoken have questioned the feasibility of the second and third methods.

1. PCA pumps are connected to computers in the pharmacy and distributed "ready to use": For each new PCA infusion, the pharmacy sends up a kit containing a pump already programmed with the correct protocol for the patient, an administration set, and the correct drug vial.
2. A computer with pump programming is placed near the storage area for PCA medications. A clinician brings the pump into the storage area, obtains the correct medication vial, and selects a protocol on the computer based on the patient's medication order; the pump is then connected to the computer to download the protocol before the programmed pump and the medication vial are brought into the patient's room. Clinicians expressed concern that typical medication storage areas would not have enough space to accommodate a computer and clinicians programming their pumps.
3. Several PDAs or mobile computers with protocol software are made available in each care area. When setting up a PCA infusion, a clinician brings a computer into the patient's room and connects it to the pump at the bedside. Clinicians expressed concern that managing the availability and security of such computers could be onerous.

Any of these approaches entails a change in workflow. Before considering the purchase of a pump with computer-based pump-programming software, facilities should ensure that their clinicians will be able to accommodate this workflow. It will be necessary to investigate the current workflow in care areas in which PCA therapy is administered, consider the changes that may have to occur in order to use computer-based pump-programming systems, and use these systems on a trial basis before purchase. ◆

bar-code scanner and therefore no way of ensuring that a clinician selects the right drug from the drug library. (For example, what if the clinician inserts a drug vial of 5 mg/mL morphine but chooses "1 mg/mL morphine" from the drug or protocol library?) However, one pump with a dose error reduction system just added a bar-coding module (not tested by ECRI) and also offers the ability to detect a specific brand of prefilled morphine 1:1 syringe by its barrel size and offer only this drug concentration to the clinician.

- One pump that currently offers an integrated bar-code scanner lacks a dose error reduction system and therefore cannot identify inappropriate continuous and bolus dose settings for initial and subsequent programming.

Physiologic Monitoring during PCA Therapy

One of the most difficult aspects of PCA therapy is tailoring the therapy to a patient's unique needs. Because each patient's response to a particular drug and dose is different, there is often a fine line between a patient who receives effective pain control and a patient who is overmedicated. Consequently, clinicians must always be on the lookout for symptoms of oversedation, particularly respiratory depression. In very acute care settings, these risks are widely recognized and can be kept to a minimum because patients in such settings are usually monitored continuously. However, it is becoming increasingly common for patients to undergo PCA therapy in settings where they do not receive continuous monitoring and where clinicians may be less aware of the risks.

Monitoring PCA patients using pulse oximetry (SpO_2) and capnography ($ETCO_2$) as an adjunct to regular check-ins and pain assessments allows clinicians to quickly identify and respond to patients experiencing respiratory depression. Awareness of the effectiveness of monitoring as a safety tool for PCA was raised by a recent letter to the editor of the *American Journal of Health-Systems Pharmacy*.* The letter describes the results of clinical trials at St. Joseph's/Candler Health System (SJCHS) in Savannah, Georgia. SJCHS implemented the Alaris System PCA Module (evaluated on page 16 of this issue) in conjunction with Alaris's SpO_2 and $ETCO_2$ monitoring modules. These modules provided continuous monitoring of patients, recorded physiologic values and PCA dosing activity in detailed history and trending reports, and, most importantly, alerted clinicians whenever physiologic values fell below hospital-specified limits (for example, if the respiration rate fell below X breaths per minute). Clinicians at SJCHS were able to identify five cases in which patients developed respiratory depression during the course of PCA therapy—including three cases of previously undiagnosed sleep apnea—during the first three weeks of implementation.**

Granted, continuous physiologic monitoring during PCA therapy is not the current standard of care and adds expense to the stay of a patient. But we believe that it can be an effective means of identifying PCA patients experiencing respiratory complications as a result of oversedation. Facilities may want to review their current policies on physiologic monitoring and PCA use, and may want to consider placing patients under continuous monitoring for select parameters—especially those patients who are predisposed to respiratory complications (e.g., those with coexisting conditions such as sleep apnea or those who require higher doses of medication to achieve adequate pain relief).

While Alaris is the only manufacturer that currently offers a system with both PCA and monitoring options, facilities could achieve many of the same advantages seen by SJCHS through the use of stand-alone physiologic monitors. (This approach would not offer the display of trending data with PCA dosing and physiologic monitoring data.) Several manufacturers now offer small bedside physiologic monitors intended for monitoring a limited number of parameters in low-acuity-care areas, and these units may offer a cost-effective option for hospitals that are not using the Alaris System. ◆

* Maddox RR, Williams CK, Fields M. Respiratory monitoring in patient-controlled analgesia. *Am J Health Syst Pharm* 2004 Dec 15;61(24):2628, 2635.

** Software Version 8 of the Alaris System PCA module, released in September 2005, offers the additional ability to pause PCA therapy when a patient's vital signs fall below facility-customized limits (see the inset on page 17).

In ideal circumstances, all PCA pumps would provide an onboard bar-code reader (or some other means of auto-programming that includes drug recognition) that works in conjunction with a good dose error reduction system. However, only one pump currently offers this combination.

Note that these error-reduction features are likely to have different requirements when used for PCA pumps than they do with general-purpose pumps. For example, general-purpose pumps are used to deliver a wide variety of medications throughout a facility, so a dose error reduction system used for these pumps needs to present an extensive menu of drugs to choose from. In contrast, PCA pumps are typically used to deliver only a limited number of pain medications, so the dose error reduction system for such a pump only needs to offer—and for the sake of convenience *should* only offer—a comparatively small selection of the most commonly used analgesics.

PHYSIOLOGIC MONITORING AS A SAFETY TOOL

One manufacturer has introduced monitoring modules to identify patients with respiratory depression, a common hazard of PCA therapy. See "Physiologic Monitoring during PCA Therapy" on page 10 for a discussion of the possible advantages of such capabilities.

Evaluation Protocol

About Our Testing

A list of the tests we performed is provided in the inset on this page. We also performed qualitative assessment of all evaluated pumps using the procedure for infusion devices (Procedure No. 416-20010301-01) provided in the *Health Devices Inspection and Preventive Maintenance System*.*

We conducted all flow and pressure tests using deionized water from prefilled bags hung as high above the pump as the administration set would allow. For syringe-based pumps, we performed all flow and pressure tests using deionized water from an appropriately sized new syringe.

We measured all pressures using DNI Nevada Model 207 and 207B digital pressure meters (accurate to within 1%).

Flow and dose volume accuracy was measured using a Mettler Model AE163 electronic balance to weigh the fluid delivered through a 20-gauge orifice into a flask of deionized water with oil floating on the surface (to minimize evaporation).

Revisions to Our Protocol

CHANGED CRITERIA

We previously evaluated PCA pumps in our May 2001 and September-October 2001 issues. For the current study, we made a number of revisions to our criteria. They include changes to our requirements for the capacity of the dose-delivery system and reservoir, the length of time a battery-only pump should be able to operate, the methods used to protect against free-flow, and the maximum occlusion pressure. Ultimately, those changes had little or no impact on our findings for the evaluated pumps, so we have not detailed them here. A complete listing of our current criteria and test methods is available on request.

NEW CRITERIA

We added a new set of criteria covering advanced error-reduction features—principally integrated bar-code readers, dose error reduction systems, and computer-based pump-programming applications. Our assessment of a pump's advanced error-reduction features is based on the following criteria:

- Initial programming using these features should include the drug name, concentration, dosing units, initial settings for bolus doses, continuous (basal) flow setting if selected, lockout intervals, and time-based dosing limits.
- It should be possible to set dose limits (i.e., maximum and minimum settings for bolus doses and continuous doses) for subsequent reprogramming of the pump, as well as maximum rate limits (in mL/hr) and lockout intervals for each order.
- A clear indication should be displayed on the pump any time that a preset dosing protocol or dose limits are not in use or that limits have been overridden. Indication of an overridden limit should be observable at least every

Tests Performed

Human Factors
- Fluid Capacity
- Displayed Information
- Dose-Request Control
- Ease of Use

Performance
- Flow and Dose-Volume Accuracy
- Battery Power
- Memory Functions
- Data Logs

General Safety Features
- Free-Flow Protection
- Dose-Interval Range (Lockout)
- Occlusion (Overpressure) Alarm
- Alarm Characteristics
- Resistance to Tampering and Accidents
- Drug/Dose Calculation

Advanced Error-Reduction Features

* The *Health Devices Inspection and Preventive Maintenance (IPM) System* includes more than 70 procedures covering more than 150 devices. For information about the *IPM System*, contact Tim Rutter at +1 (610) 825-6000, ext. 5168, or at ipm@ecri.org.

few seconds (e.g., if part of a scrolling display) so that this status will be quickly recognized by clinicians.

- The system should permit a facility to specifically configure its protocol/drug library to the facility's current ordering and delivery practices (i.e., protocol names, drug names, concentrations, and dosing units should be customizable).
- Advanced error-reduction software should be designed to encourage consistent use by being simple to operate and by requiring minimal extra steps or time compared to conventional PCA programming.
- The pump should display the protocol/drug name and dosing information at all times. The display should include enough characters for clinicians to easily interpret the drug being infused and the dosing units.
- PCA pumps with dose error reduction systems should have either (1) a specific dose error reduction system alarm and event log separate from the pump's primary data log or (2) the ability to pull dose error reduction system alarms and events from the pump's main log. This functionality will allow facilities to track limit overrides and programming changes that have occurred as a result of overlimit or underlimit warnings. The log should retain data for more than one year and should be downloadable for spreadsheet analysis.
- Ideally, pumps with advanced error-reduction features intended for use in an outpatient setting (e.g., home care) should permit remote communication (e.g., over a modem) to allow clinicians to perform remote diagnostics and chart history.
- Manufacturers should provide facility-based support with the implementation of advanced safety features. This support includes assistance with:
  - — Coordination of appropriate decision-making staff from areas such as pharmacy, nursing, and medicine
  - — Developing a protocol/drug library consistent with the facility's ordering and delivery practices
  - — Developing dose limits for each protocol/drug
  - — Developing protocol/drug-specific parameters—such as concentrations(s), maximum infusion rate, patient weight, and volume to be infused (VTBI)—if available
  - — Training clinicians in the effective use of the pump and its advanced safety features

Product Profiles

Evaluated Products

NEWLY TESTED MODELS

For this Evaluation, we tested the following PCA pumps. Five of them are evaluated for the first time; the sixth, the Smiths Medical CADD-Prizm PCS II, was originally evaluated in our September-October 2001 issue, when it was sold under the Deltec name. Because this product now incorporates automated pump-programming software, we have tested it again.

- Alaris System PCA Module . . . . . page 16
- Baxter Syndeo PCA Syringe Pump . . . . page 19
- Curlin Medical 4000 CMS . . . . . page 21
- Hospira GemStar . . . . . page 23
- Hospira LifeCare PCA 3 . . . . . page 25
- Smiths Medical CADD-Prizm PCS II. . . page 27

PREVIOUSLY EVALUATED MODELS

The following products were evaluated in our May 2001 issue and are still on the market. Because these products do not offer advanced safety technologies—and are therefore Not Recommended regardless of any performance differences—we have not retested them or investigated any changes that have been made to them. We do, however, compare these products to the newly evaluated models in the Conclusions section on page 30.

- Baxter Ipump Pain Management System
- Baxter PCA II
- McKinley EpM
- SIMS Graseby 3300 PCA
- Smiths Medical (formerly SIMS Deltec) CADD-Legacy PCA Model 6300

Three of the pumps that we evaluated in 2001 are no longer actively marketed and are not included in this Evaluation: the Abbott (now Hospira) Pain Manager (APM) II, Abbott (now Hospira) LifeCare 4100 PCA Plus II, and Sorenson MicroJet PCA.

The Baxter 6060 Multi-Therapy Infusion Pump, which we also evaluated in 2001, was recalled by the supplier in November 2005 and is also excluded from this study. See "Status of Three Baxter PCA Pumps" on page 15 for more information.

About Our Results and Ratings

PRESENTATION OF RESULTS

In reporting our test results, we present only those findings that we determined to be significant. We do not discuss results for tests in which a unit simply met our criteria or did not have any remarkable features. However, we do provide a table listing ECRI's judgment of the unit's performance for all tests according to the following scheme:

Excellent. The unit possesses a feature or performs at a level that would likely be considered favorable during the selection process.

Good. The unit performs satisfactorily. In general, any advantages of the unit balance or outweigh any disadvantages.

Fair. The unit either does not perform satisfactorily or has a noteworthy deficiency or limitation. However, the failure, deficiency, or limitation is not likely to (1) cause an adverse clinical outcome, (2) significantly affect the overall performance of the unit, or (3) place an excessive burden on those who purchase, use, or service the unit.

Poor. The unit does not perform satisfactorily, and its deficiencies or limitations are likely to (1) adversely affect the clinical outcome, (2) significantly affect the overall performance of the unit, or (3) place an excessive burden on those who purchase, use, or service the unit.

Currency Exchange Rates

Prices listed in *Health Devices* are typically presented in U.S. dollars. The exchange rates below can be used to provide rough cost comparisons in a number of currencies.

Equivalent for $1 (U.S.) on January 11, 2006

Currency	Rate*	Currency	Rate*
Australian Dollars	1.33	Malaysian Ringgit	3.75
Brazilian Real	2.27	New Zealand Dollars	1.44
British Pounds	0.57	Saudi Arabian Riyal	3.75
Canadian Dollars	1.16	Singapore Dollars	1.63
Euro	0.83	South African Rand	6.06
Hong Kong Dollars	7.75	Turkish New Lira	1.34
Japanese Yen	114.25		

*The exchange rates listed were obtained through online sources on the date indicated. Because these rates are variable, the information in this table should be used for approximations only. Also, readers should recognize that actual purchase prices in particular regions may vary from the prices used for this study.

Status of Three Baxter PCA Pumps

Two Are on Hold, One Has Been Withdrawn

Ipump and Syndeo Shipments on Hold

The Baxter Ipump Pain Management System and the Syndeo PCA Syringe Pump are currently not being shipped to new accounts.

- **Ipump.** Shipments are on hold pending the release of a software revision designed to remedy fluid-delivery problems affecting the pump. (These problems are described in *Health Devices Alerts* Action Item A6169, "Baxter Ipump Pain Management Systems: Several Failures May Occur.") A release date for this revision has not been announced.
- **Syndeo.** This pump has been on voluntary hold by Baxter and was the subject of a seizure by the U.S. Food and Drug Administration (FDA) in the fall of 2005. That seizure also included the Baxter Colleague general-purpose pump. (We discussed some of the issues related to the Colleague in our December 2005 issue; see the Evaluation Update on page 421 of that issue.) FDA cited improper manufacturing controls as the reason for seizing the Syndeo.

At press time, it was not known when either of these products would resume shipping.

6060 Withdrawn

On November 14, 2005, Baxter issued an Urgent Product Recall of the 6060 Multi-Therapy Infusion Pump. In the recall, Baxter stated that it "has received reports of failures within the PCA profile as well as reports of incidents that result in interruptions of therapy in various profiles." Consequently, the company said, it was initiating a controlled withdrawal of the product from hospitals.

Because the 6060 is being withdrawn from use, we have removed it from this study. ◆

RATINGS RATIONALE

Because PCA pumps often have been cited as examples of devices that contribute to medical error, the ability of each device to encourage safe use and resist tampering weighed heavily in our ratings. We based our ratings on two major safety concerns: ease of use and advanced error-reduction features for minimizing medication errors.

To be rated at least Acceptable, pumps must not only perform satisfactorily overall but must also (1) encourage safe use by allowing clinicians to easily program and monitor the pump's fluid delivery and (2) offer a dose error reduction system, integrated bar-code scanner, or computer-based pump-programming feature that satisfies most or all of our criteria for this function. Pumps that meet the first condition but that lack adequate advanced error-reduction features are rated Not Recommended for purchase; that is, we consider these models less desirable than models that offer those features.

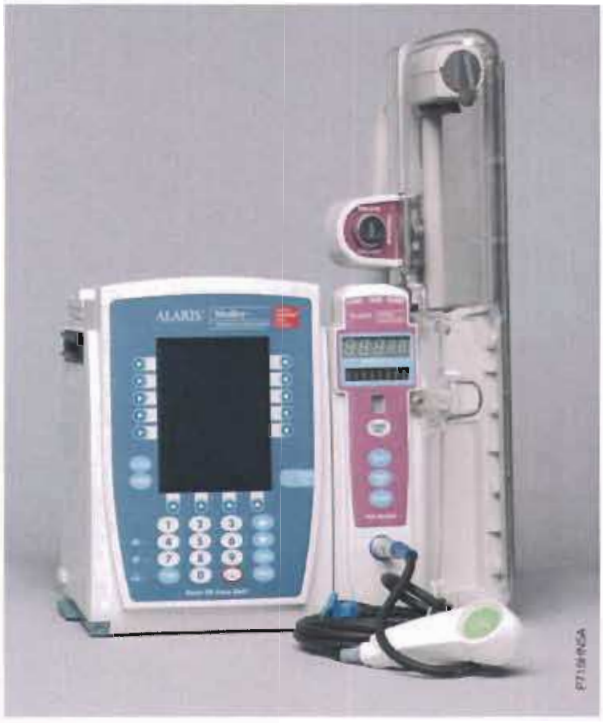
Alaris System PCA Module

Supplier. Alaris Medical Systems Inc., Subsidiary of Cardinal Health Inc. [308442], San Diego, California (USA); +1 (800) 854-7128, +1 (858) 458-7000; www.alarismed.com

Product availability. Introduced December 2004. Marketed in Canada and the United States.

Product Description

The Alaris PCA module is a syringe driver sold as a component of the pole-mounted Alaris System. The Alaris System offers large-volume, syringe, and PCA pumping modules, as well as pulse oximetry (SpO_2) and end-tidal carbon dioxide ($ETCO_2$) modules. Therefore, it may be purchased for PCA-only use or for use in combination with other general-purpose infusion or monitoring modules. The Alaris System offers Alaris's Guardrails software, which provides a number of applications including a dose error reduction system plus wireless pump connectivity that allows the pump to send event logs to and receive drug libraries from a central server. An integrated bar-code imaging module for clinician, patient, and drug-container identification was released in November 2005. The PCA module offers a contoured dose-request pendant with a lighted switch. This pump is not intended for home care use.



Rating: Preferred

The Alaris System PCA module is an easy-to-use pump with a comprehensive and configurable dose error reduction system and no major disadvantages. This pump would be a particularly good choice for hospitals that wish to use the Alaris System's monitoring capabilities or its general-purpose or syringe modules either now or in the future. It is not intended for home care use.

Pros

- Guardrails dose error reduction software provides dosing limits and offers excellent analysis of logged alerts and alarms to help tailor drug library to clinical needs; has seen extensive successful use for PCA applications
- Has bar-code function (released too late for testing by ECRI) for identifying clinician, patient, and drug container (requires users to print bar codes or order syringes that have bar coding)
- Offers hospital-configurable lighted dose-request pendant

Cons. None worth mentioning ◆

Significant Test Results

Human Factors

Overall human factors are excellent. Displayed information, dose-request control, and general ease of use are also excellent.

The pump provides unique history information, in that users can vary the time scale of reports to show the total amount of drug delivered, doses requested, and doses delivered for the past 24, 12, 8, 4, 2, or 1 hours.

The hospital-configurable lighted dose-request pendant is a plus. In one configuration, for example, the pendant indicates when a dose is available (steady light), being delivered (blinking light), or not available due to a lockout or

Test Results
Alaris System PCA Module

Human factors	**Excellent**
Fluid capacity	Good
Displayed information	Excellent
Dose-request control	Excellent
Ease of use	Excellent
Performance	**Good**
Flow and dose-volume accuracy	Good
Battery power	Good
Memory functions	Good
Data logs	Excellent
General safety features	**Excellent**
Free-flow protection	Good
Dose-interval range (lockout)	Good
Occlusion (overpressure) alarm	Good
Alarm characteristics	Excellent
Resistance to tampering and accidents	Good
Drug/dose calculation	Excellent
Advanced error-reduction features	**Excellent**

a time-based dosing limit (unlit). The pendant is brightly colored and contoured to fit the patient's hand.

The large, comprehensive display screen provides step-by-step prompts that are easy to follow.

Performance

Overall performance is good. The pump's data logs are excellent: They can be downloaded to a computer using Alaris's Continuous Quality Improvement (CQI) application, a component of the Guardrails software. This software provides analysis of the dose error reduction system alarm and event logs to help hospitals better tailor the drug library to clinical needs and improve clinical practice.

General Safety Features

Safety features are excellent overall: Escalating alarm volume draws attention to problems, and clear text and diagrams give the alarm's cause and provide the user with instructions for appropriate follow-up. In addition, all delivery settings are presented in a single confirmation screen.

Advanced Error-Reduction Features

The pump's error-reduction features are excellent. Alaris's Guardrails dose error reduction software includes a computer-based drug library editor for developing and maintaining facility-customized drug libraries and data mining/reporting software for analyzing alert and alarm logs for continuous quality improvement. A significant advantage is that this software has seen extensive implementation in both PCA and general-purpose pumping modules and has proven effective in a hospital environment. In addition, the pump can identify one brand of prefilled syringe by its barrel size: Only morphine 1:1 is offered as a drug selection when an International Medication Systems (IMS) Pump-Jet 30 cc prefilled morphine 1 mg/mL syringe is loaded in the device. Although the pump does not offer a continuous display of out-of-limit programming, it offers an audible and visual alert during the programming process for any programming parameters that are outside the limits for the particular drug entity selected. The pump asks for confirmation in the case of soft-limit violations and does not accept settings that violate hard limits. The pump also displays the limits at the time of each alert (e.g., "Entry of 10 Is Outside the Limits of 1-5").

Another plus of the Guardrails software is that it allows hospitals to develop drug-specific or therapy-specific drug entities (e.g., "1 mg/mL Morphine," "Hydromorphone Post-Operative," "50-70 kg Pediatric Morphine"). These

Alaris System Software Version 8 Now Available

Software Version 8 for the Alaris System was released in September 2005. This software version includes PCA enhancements such as:

- The ability to automatically interrupt PCA therapy if a patient's pulse oximetry or breaths per minute fall below hospital-specified limits
- Support for an integrated bar-code imaging module for clinician, patient, and drug-container identification (the module itself was released in November 2005)
- The ability to accommodate intermittent and secondary infusions and set starting doses for each drug entity
- A reconfigured drug library in which a clinician first selects the care area, then the drug name, therapy (e.g., acute pain, chronic pain), and concentration; this allows hospitals to provide access to more than one drug entity under each drug name and may make selecting a drug entity more intuitive

ECRI has not evaluated this software version. ◆

entities include hard (cannot be overridden) or soft (can be overridden with confirmation) dosing limits for continuous or bolus delivery settings, lockout limits, limits on manually entered drug concentrations, and clinical advisories for each drug entity.

The Alaris System's bar-code module is designed to provide clinician, patient, and drug-container identification. We have not tested this feature; however, we believe that it will effectively populate pump settings and automatically place the pump under the correct dose error reduction limits for subsequent programming.

The PCA module requires users to program within the drug library (i.e., no generic infusions are permitted). Although this requirement would not be appropriate for general-purpose pumps (due to the need for generic programming during an emergency or when new fluids are not part of the drug library), it is an advantage for PCA use, in which a limited number of known drugs are used. For more information on Guardrails dose error reduction system software, please see our October 2002 Evaluation of the general-purpose pumping module of the Alaris System (which was then called the Alaris Medley Medication Safety System).

Baxter Syndeo PCA Syringe Pump

Supplier. Baxter Healthcare Corp., Medication Delivery/Infusion Systems [393248], Round Lake, Illinois (USA); +1 (888) 229-0001, +1 (847) 948-2000; www.infusingsolutions.com

Product availability. Introduced October 2003. Marketed in the United States.

Note. This product is currently on hold by the supplier; no units are being shipped to new accounts. See "Status of Three Baxter PCA Pumps" on page 15 for more information.

Product Description

The Baxter Syndeo PCA Syringe Pump is a pole-mounted syringe pump with a large touchscreen display and contoured dose-request pendant. This pump is not intended for home care use.

Significant Test Results

Human Factors

Human factors are only fair overall because the pump does not display the drug dosing units, concentration, or continuous or PCA dose settings while the pump is running. To view these settings, the user must press the pump's "History" button.

Another drawback is that the pump will provide the same tone in response to both valid and invalid medication requests unless its Dose Tone feature is disabled. This means the patient will have no way of knowing that a request was invalid (because it was made during a lockout interval or violated a dose limit) and that the requested bolus will not be delivered.

We judged ease of use as excellent, thanks to the large, comprehensive display screen, which provides step-by-step prompts that are easy to follow. An additional advantage is that the pendant is brightly colored and contoured to fit the patient's hand.

Rating: Not Recommended

While the Baxter Syndeo's delivery capabilities are adequate, it lacks advanced safety technologies and has a number of human factors drawbacks.

Pros

- Large, comprehensive display provides easy-to-follow prompts
- Clear text and diagrams pinpoint the location and nature of alarms, instruct user on follow-up
- Drug/dose setting presented on a single confirmation screen

Cons

- Product is on hold by supplier; no units are currently being shipped to new accounts; see "Status of Three Baxter PCA Pumps" on page 15 for more information
- Does not offer advanced error-reduction features
- Does not display dosing units, concentration, or dose settings while the pump is running
- Because it lacks a power cord, it requires the replacement of four D-cell batteries at least once a week (depending on the rate of fluid delivery), which is an unnecessary inconvenience for hospitals ◆

Performance

Overall performance is good, although battery power and data logs are judged only fair. A major disadvantage is that, although this pump is intended for hospital use, it does not come with a power cord; instead, it runs only from four D-cell batteries. Baxter states that the pumps provide sufficient power for 10 days of therapy; however, pump use can be highly variable. To ensure that power doesn't run out, hospitals would need to replace the batteries in each pump at least weekly (and perhaps more often, depending on the rate of fluid delivery). We believe that this is overly onerous to clinicians, not to mention expensive. Baxter has stated that hospitals may choose to purchase additional battery cartridges for these pumps and to stock cartridges filled with fresh batteries in care areas for a quick swap-out by clinicians. Baxter also states that it plans to offer a field-upgradable rechargeable battery pack with power cord in the future.

Test Results
Baxter Syndeo PCA Syringe Pump

Human factors	**Fair**
Fluid capacity	Good
Displayed information	Poor
Dose-request control	Good
Ease of use	Excellent
Performance	**Good**
Flow and dose-volume accuracy	Good
Battery power	Fair
Memory functions	Good
Data logs	Fair
General safety features	**Excellent**
Free-flow protection	Good
Dose-interval range (lockout)	Good
Occlusion (overpressure) alarm	Good
Alarm characteristics	Excellent
Resistance to tampering and accidents	Good
Drug/dose calculation	Excellent
Advanced error-reduction features	**Poor**

An additional disadvantage is that the pump exhibits extended periods of no flow (over an hour in some cases) at the beginning of therapy when set to 0.1 mL/hr if a loading dose is not utilized. Although such a low flow setting is rare in PCA therapy, this problem could result in a patient being denied pain medication for a significant period of time. A loading dose should always be used with extremely low continuous rates.

In addition, the pump's Device Log, which holds the past 1,000 events, cannot be downloaded to a computer; the pump can export this log to a printer only. However, the pump's Patient History, which includes a log of events that have happened since "New Patient" was last selected, can be uploaded to a personal digital assistant (PDA) via the pump's infrared port and then loaded onto a computer for postincident analysis.

General Safety Features

Safety features are excellent: Clear text and diagrams indicate the location or nature of problems (e.g., part of the syringe is misloaded) and provide the user with instructions for appropriate follow-up. In addition, all drug/dose settings are presented on a single confirmation screen, and the pump can be configured to require a second clinician's confirmation.

Advanced Error-Reduction Features

The pump is judged poor in this area because it does not offer advanced error-reduction features. Baxter states that it plans to offer a software upgrade to include dose error reduction functionality in the future.

Curlin Medical 4000 CMS

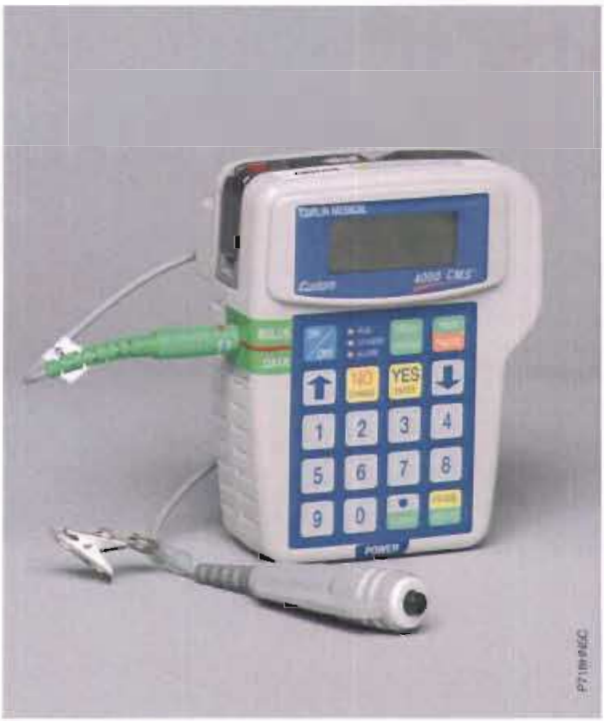
Supplier. Curlin Medical LLC [320071], Huntington Beach, California (USA); +1 (888) 487-4454, +1 (714) 893-2200; www.curlinmedical.com

Product availability. Pump introduced 2001; CMS software introduced 2002. Marketed worldwide.

Product Description

The Curlin Medical 4000 Clinical Management System, or CMS, is a multitherapy ambulatory peristaltic pump (configurable to PCA-only) that can be used for hospital or home care applications. Accessories for the pump include a pole-mounting bracket and lockboxes.

The 4000 CMS is sold with Curlin Medical's PC-based CMS programming application. This application can send a standardized dosing protocol via a wired connection from a computer or personal digital assistant (PDA) to the pump. The dosing protocol includes dosing limits for subsequent programming changes. The CMS software has been used successfully for automatic pump programming in home care environments but has not yet been used in a hospital setting.



Rating: Acceptable

The Curlin Medical 4000 CMS is an easy-to-use pump with good flow accuracy and continuity. This pump would be a good choice for outpatient clinics, home care applications, and hospitals that desire a small, ambulatory-style pump.

Pros

- CMS programming software allows drug-specific, therapy-specific, or patient-specific dosing protocols to automatically populate pump settings; only hard rate limits are available
- Ambulatory design allows fluid delivery from a wide variety of bags and syringes

Cons

- Some facilities may not be able to accommodate the workflow needed to use the automated pump-programming feature
- Operator dose review is not required after programming ◆

Significant Test Results

Human Factors

Human factors are good overall. The pump's ambulatory design allows fluid delivery from a wide variety of bags and syringes.

Displayed information is excellent: The pump shows information clearly and quickly, eliminating the need to scroll through to view settings. The screen provides displays in two font sizes; the smaller font makes the most of the unit's small screen and allows users to see more information quickly, while the larger font is big enough to catch users' attention. At all times, the pump's display cycles through each delivery variable (e.g., PCA bolus size, total amount of drug delivered) one at a time in the larger font. This sequence of large-font screens alternates with two small-font screens that display all delivery information. A minor disadvantage is that the smaller font can be difficult for users with poor eyesight to read.

Ease of use is only fair. The set requires a user to twist and remove a flange to activate the pump's free-flow

protection mechanism, which can be confusing to inexperienced operators. The pump will not allow a set to be installed if this mechanism has not been activated.

Performance

Overall performance is good. On power-up, the pump offers the options of resuming therapy, repeating the last therapy, or reprogramming the pump altogether. However, there is no prompt to the clinician to clear the pump after an extended power-off (although this option is available by selecting "New Rx" from the startup menu).

General Safety Features

Safety features are good overall. An advantage is that the pump only accepts dedicated sets that offer free-flow protection.

The occlusion (overpressure) alarm is excellent: The pump allows users to select either of two pressure limits—low (measured by ECRI as 6 psi) or high (measured as 14 psi). This could be useful for reducing nuisance alarms in high-pressure therapies such as epidural administration, while allowing a low-pressure setting for IV administration.

Test Results
Curlin Medical 4000 CMS

Human factors	**Good**
Fluid capacity	Good
Displayed information	Excellent
Dose-request control	Good
Ease of use	Fair
Performance	**Good**
Flow and dose-volume accuracy	Good
Battery power	Good
Memory functions	Good
Data logs	Good
General safety features	**Good**
Free-flow protection	Good
Dose-interval range (lockout)	Good
Occlusion (overpressure) alarm	Excellent
Alarm characteristics	Good
Resistance to tampering and accidents	Fair
Drug/dose calculation	Fair
Advanced error-reduction features	**Good**

Resistance to tampering and accidents is only fair. The pump uses terms that inexperienced users may not be familiar with. For example, it offers a dosing limit in the form of "# Bolus/Hour" as well as the more familiar one-hour dosing limit in mg.

Drug/dose calculation is also only fair, since operator review of programming is not required before starting operation. The review screen is optional; it also uses the smaller font, which may be difficult for some users to read, and requires users to scroll down (by hitting Enter) for each item, which can be cumbersome.

Advanced Error-Reduction Features

The pump's error-reduction features are good. Curlin Medical's CMS PC-based pump-programming software allows a hospital to develop drug-specific, therapy-specific, or (if desired) patient-specific dosing protocols that are stored on a computer or Palm personal digital assistant (PDA) and sent via a connecting cable to a pump. The protocols will automatically populate pump settings such as drug concentration, continuous and bolus delivery settings, lockout interval, and time-based dosing limits. Through a function labeled Titrate (available in the Options menu), the pump offers limits on maximum continual and bolus delivery values, minimum lockout between boluses, and maximum number of boluses per hour. Only hard limits are available—settings that are outside the limits are not accepted. If a user needs to set the pump to a rate outside the hard limits, the user must enter the Options menu, disable the Titrate function, and then reprogram the pump.

The pump also offers an audible and visual alert for any programming parameters that are outside the limits for the protocol if the user has sent a protocol to the pump from a computer equipped with CMS software.

A caution about any pump-programming software: Because it requires protocols to be downloaded to the pump before each infusion, such software could impede clinicians' workflow. Facilities considering the Curlin Medical pump should be sure they can adapt their workflow to the requirements of the pump-programming software. For further discussion, see "Implementing Computer-Based Pump-Programming Systems" on page 9.

Hospira GemStar

Supplier. Hospira Inc. [440680], Lake Forest, Illinois (USA); +1 (877) 946-7747, +1 (847) 937-6100; www.hospira.com

Product availability. Introduced March 2000. Marketed worldwide.

Product Description

The Hospira GemStar is a multitherapy ambulatory peristaltic pump (configurable to PCA-only) with an optional pole-mounting bracket (locking or nonlocking), two configurations of lockboxes, ambulatory carrying cases, and multiple power sources. The pump can be purchased in one of three color schemes: blue (indicating intravenous PCA), yellow (epidural PCA), and gray. This pump is intended for both hospital and home care use.

Significant Test Results

Human Factors

Human factors are rated good. An advantage is that the pump's ambulatory design allows fluid delivery from a wide variety of bags, syringes, vials, and bottles.

Rating: Not Recommended

The Hospira GemStar is an easy-to-use pump that has few operational disadvantages. However, we don't recommend its purchase because it lacks advanced error-reduction features.

Pros

- Allows fluid delivery from a wide variety of containers
- Offers several operational options on power-up
- Provides clear displays and easy-to-follow prompts

Cons

- Does not offer advanced error-reduction features
- "Check IV Set" alarm does not clearly identify reason for alarm
- Lockbox can be difficult to assemble and load ◆

Performance

Overall performance is good. On power-up, the pump offers the options of resuming therapy, reprogramming the pump and clearing only the shift history (for use when the pump is being reprogrammed but will stay on the same patient), or reprogramming the pump and clearing the patient history altogether (for use on a new patient).

General Safety Features

Safety features are good overall. An advantage is that the pump accepts only those dedicated sets that offer free-flow protection.

The occlusion (overpressure) alarm is excellent: The pump allows users to select from among three pressure limits: low (7 psi), medium (14 psi), and high (30 psi). Although we do not anticipate that most facilities will need the high setting, the low and medium settings could be useful for reducing nuisance alarms in high-pressure therapies such as epidural administration, while providing a low-pressure setting for IV administration. (The high setting can be inactivated through the pump's service menu.)

Alarm characteristics are only fair: The "Check IV Set" alarm—which is often triggered by an administration set

Test Results
Hospira GemStar

Human factors	**Good**
Fluid capacity	Good
Displayed information	Good
Dose-request control	Good
Ease of use	Good
Performance	**Good**
Flow and dose-volume accuracy	Good
Battery power	Good
Memory functions	Good
Data logs	Good
General safety features	**Good**
Free-flow protection	Good
Dose-interval range (lockout)	Good
Occlusion (overpressure) alarm	Excellent
Alarm characteristics	Fair
Resistance to tampering and accidents	Fair
Drug/dose calculation	Good
Advanced error-reduction features	**Poor**

that is not fully seated—may be difficult for users to respond to because it does not clearly identify the problem.

Resistance to tampering and accidents is also only fair: The pump's lockbox is complex to assemble, and inexperienced users may have difficulty loading the pump and fluid container into the lockbox and closing the box successfully.

Advanced Error-Reduction Features

The pump is judged poor in this area because it does not offer advanced error-reduction features.

Hospira LifeCare PCA 3

Supplier. Hospira Inc. [440680], Lake Forest, Illinois (USA); +1 (877) 946-7747, +1 (847) 937-6100; www.hospira.com

Product availability. Introduced October 2002. Marketed in Canada and the United States.

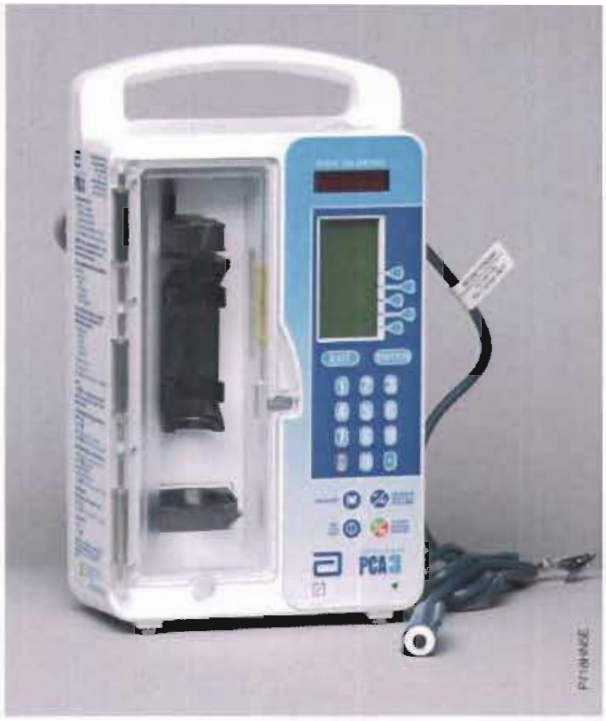
Product Description

The Hospira LifeCare PCA 3 is a pole-mounted syringe driver that delivers medications from proprietary 30 mL Hospira syringes (available empty sterile or prefilled with morphine or meperidine). The pump has an integrated bar-code reader to identify the drug name and concentration of labeled syringes as they are loaded into the pump. This pump also offers Profiles, a limited pump-programming function that allows hospitals to store up to 10 standardized dosing protocols tied to specific prefilled drug vials. This pump is not intended for home care use.

Significant Test Results

Human Factors

Human factors are excellent: The pump displays either the drug name and concentration or "Custom Vial" (if not a prefilled syringe) at all times as verified by the bar-code scanner. Also, the large, comprehensive display screen provides step-by-step prompts that are easy to follow. The pump comes with an instructional tip sheet to be attached to its handle, and simple instructions are printed on the side of the pump for loading a syringe and beginning therapy.



The pump accepts only proprietary Hospira syringes. This may be a disadvantage for facilities that wish to use medications from other suppliers; these facilities will need to fill Hospira's empty sterile syringes in-house.

Performance

Overall performance is good. A minor disadvantage is that the pump exhibits 15% overdelivery for the first two hours of therapy when set to 0.1 mL/hr. This low rate is rarely used for PCA therapy, however.

Rating: Preferred

The Hospira LifeCare PCA 3 is an easy-to-use pump that has few disadvantages. It would be a good choice for hospitals that wish to purchase prefilled (morphine and meperidine) drug syringes. It is not intended for home care use.

Pros

- Bar-code reader should eliminate wrong-drug and wrong-concentration programming errors; has proven effective in extensive use
- Profiles software offers limited automatic pump programming—allows up to 10 standardized dosing protocols to be developed and tied to particular Hospira prefilled drug vials
- Large, comprehensive display provides easy-to-follow prompts

Cons

- Lacks dose error reduction system
- Accepts only proprietary Hospira syringes
- Releases postocclusion bolus averaging 1.5 mL if instructions for safely releasing postocclusion boluses are not followed ◆